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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,795	11/17/2003	Timothy A. Stewart	P1219P1C1	5748

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,795	STEWART ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 14-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/5*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1-7, 9, 10 and 14 have been amended, claims 11-13 have been cancelled and claims 22-36 have been added as requested in the amendment filed on January 18, 2005. Following the amendment, claims 1-10 and 14-36 are pending in the instant application.

Claims 1-10 and 14-36 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 18, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

5. The disclosure stands objected to for reasons of record in section 3 of Paper mailed on July 16, 2004. Applicant's explanation regarding citations to World Wide Web sites not being machine executable (bottom at page 9 continuing to page 10 of the Response) are not persuasive because the citations fall into category of browser-executable codes and, therefore, are subject to objection in accordance with MPEP § 608.01.

Claim Objections

6. Claim 14, as amended, is objected to because of the following informalities: "claim 1 or 4" should be "Claims 1 or 4", perhaps. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 1, 5, 7, 14-15, 17-21, as amended, and new claims 22-25, 28-33 and 35-36 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record as applied to claims 1, 5-7, 14-15 and 17-21 in section 5 of Paper mailed on July 16, 2004. Briefly, the instant specification, while being enabling for an isolated nucleic molecule comprising nucleotide sequence 530-1111 of SEQ ID NO: 1, which encodes an FGF-19 polypeptide comprising amino acid sequence of 23-216 of SEQ ID NO: 2, does not reasonably provide enablement for any other isolated nucleic acid molecules specifically recited in claims 1, 5, 7, 14-15, 17-21, 22-25, 28-33 and 35-36. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

At pages 10-11 of the Response, Applicant summarizes the claimed subject matter and refers to appropriate sections of MPEP pertained to proper analysis of enablement of the disclosure. Applicant's review of the issue of enablement, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes an enabled disclosure. Applicant submits that, first, "The specification teaches amino acid and nucleic acid sequence of FGF-19"; second, that it provides methods on how determine percent identity and activity of FGF-19 molecules, and, therefore, no undue experimentation to determine how to make and use the full scope of the

claimed nucleic acids would be required in order to practice the instant invention (bottom at page 11, continuing to page 12 of the Response). Applicant's arguments have been fully considered but are not deemed to be persuasive for reasons that follow.

Applicant has taken the position that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of essentially limitless breadth as long as the specification provides one with the ability to test any particular embodiment, which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. Applicant's "make and test" position is inconsistent with the decisions *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988), which was cited as the judicial basis for the instant rejection in the previous office action, and in *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970), which held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment

provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved" (emphasis added).

Claims 1, 5, 7, 14-15, 17-21, 22-25, 28-33 and 35-36 encompass nucleic acids with a limited sequence similarity to the instant disclosed nucleic acid encoding FGF-19 polypeptide of amino acid residues 23 to 216 of SEQ ID NO: 2. The claims also require that the claimed nucleic acids encode polypeptides with a specific set of functions, such as ability to reduce total body mass, reduce fat, level of triglycerides and free fatty acids in an individual, and increase in metabolic rate. However, the instant specification, as filed, fails to provide any guidance on how to make these polynucleotides that encode polypeptides, which meet the functional limitations of the claims. The instant specification fails to identify specific residues critical to encoding the protein, which retains functions of FGF-19. There is no analogous proteins disclosed, for which this information is known and there is no working examples provided to guide a skilled artisan in an effort to make the claimed invention. It would require undue experimentation and making a substantial inventive contribution to discover how to produce a nucleic acid encoding a functional FGF-19 protein comprising anything less than amino acid sequence of 23-216 of SEQ ID NO: 2. Whereas one can readily produce any polynucleotide, which is at least 99% identical to polynucleotide of SEQ ID NO: 1, one would have no idea, how to make a polynucleotide, which would encode a polypeptide with functional properties of FGF-19.

Therefore, for reasons fully explained in the previous office action and reasons above, the instant rejection is maintained.

8. Claims 1, 5, 7, 14-15, 17-21, as amended, and new claims 22-25, 28-33 and 35-36 are rejected under 35 U.S.C. 112, first paragraph, lack of written description, for reasons of record as applied to claims 1, 5-7, 14-15 and 17-21 in section 6 of Paper mailed on July 16, 2004.

Applicant traverses the rejection on the premises that "the sequence of SEQ ID NOS: 1 and 2, coupled with recitation of percent identity (e.g., 80% identity) readily suffices to sufficiently distinguish the claimed subject matter from other material and describe the claimed subject matter". Applicant submits that "the amino acid sequence of SEQ ID NO: 2 and/or the nucleic acid sequence of SEQ ID NO: 1 are a common feature to the claimed genus" and, further, that "identification of a particular portion of the sequence that must be conserved is not required under law" (middle at page 13 of the Response). Applicant's arguments have been fully considered but are not persuasive for reasons that follow.

As fully explained in the previous office action of record, the instant claims are directed to a genus of nucleic acid molecules, which are identified by structural similarity to a polynucleotide encoding polypeptide of SEQ ID NO: 2 having functional characteristics of FGF-19. The instant specification, as filed, fails to provide any sufficient distinguishing identifying characteristics of the claimed genus. In the absence of such written disclosure, one skilled in the art clearly cannot envision the detailed chemical structure of the encompassed genus of polynucleotides.

At middle of page 13 of the Response, Applicant argues that "the specification teaches (and methods are well-known in the art) how to generate nucleic acids encoding variant proteins,

how to calculate percent identity of nucleic acid and amino acid sequences, and provides information relating to hybridization of nucleic acids". It appears that Applicant is arguing rejections under 35 U.S.C. 112, first paragraph, lack of written description and lack of enablement, concurrently. Applicant is reminded that the written description provision of 35 U.S.C. §112 is severable from its enablement provision, therefore, reference to the ability of one skilled in the art to produce and test the claimed nucleic acid molecules with respect to the written description requirement appears to be misplaced.

The instant situation is directly analogous to that, which was addressed in *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991). The court held that:

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 U.S.P.Q. 2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated".

9. Claim 21 stands rejected under 35 U.S.C. 112, first paragraph, for reasons of record in section 7 of Paper mailed on July 16, 2004.

Applicant is advised that full analysis of the Wands factors with respect to enabling disclosure is not required in cases when the claimed subject matter contradicts the fundamental knowledge in the pertaining art (page 14 of the Response). In the instant case, claim 21 encompasses a process for producing an FGF-19 polypeptide by culturing a host cell (of claim 17) comprising a vector (of claim 14) comprising an isolated nucleic acid molecule, which is complementary to the nucleic acid molecule encoding FGF-19 polypeptide (claim 1). The instant specification fails to provide exact protocol for the claimed process and there appears to be no known teachings in the art on how to produce a polypeptide by using a nucleic acid strand complementary to the nucleic acid encoding that polypeptide. Thus, one would reasonably conclude that it would require undue experimentation and making a substantial inventive contribution for one skilled in the art before being able to successfully practice Applicant invention, as currently claimed.

9. Claims 1-4, 9, 10 and 22-27 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation of limitation "about [...] amino acids" or "about [...] nucleotides" for reasons of record in section 9 of Paper mailed on July 16, 2004. Applicant traverses the rejection on the premises that "the term "about" is accepted widely in patent practice and is clearly acceptable under the law" and refers to MPEP and case law pertaining to 35 U.S.C. 112, second paragraph (last paragraph at page 15 of the Response). Applicant's arguments have been carefully considered but are not persuasive because, as fully explained in the previous office action of record, the Examiner never stated that the term "about" always

renders claims using this terms indefinite. On the contrary, it is appropriate to employ the term "about" to define dimensions, for example. However, in the instant case, using recitation "about 23 to about 216" amino acid residues (see claim 1, for example) provides no clear definition to the structure of the claimed molecular embodiments. For example, the length of the claimed nucleic acid, as in claim 2, is vague and ambiguous because it is not clear which one of the molecular embodiments is recited in the claim, as molecule "comprising nucleotides from about 464 or about 530 to about 1111 of Figure 1 (SEQ ID NO: 1)" reads on fragments starting from any nucleotide before position 464 and ending at any nucleotide after 1111 of SEQ ID NO: 1.

With respect to Applicant's reference to other US Patents, which use the term "about" in the claims to describe the length of a polypeptide (top at page 16 of the Response), it is well settled that the prosecution of one patent application does not affect the prosecution of an unrelated application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976) (holding that "[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others"). Accordingly, Applicant's arguments with respect to other patents are unavailing.

10. Claims 14-15, 17-33 and 35-36 are indefinite for being dependent from the indefinite claims.

Double Patenting

11. Applicant is advised that should claim 1 be found allowable, claims 28-33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, claims 28-33 contain functional limitations and no structural limitations, which makes the scope of the clamed subject matter of claims 1 and 28-33 undistinguishable.

Conclusion

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

March 15, 2005